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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,580	09/25/2006	Todd D. Campbell	ETI 301	9677

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EXAMINER	
HAGOPIAN, CASEY SHEA	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
09/15/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/587,580	CAMPBELL ET AL.	
	Examiner	Art Unit	
	CASEY HAGOPIAN	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *78 and 98-115* is/are pending in the application.

5a) Of the above claim(s) *109 and 111* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *78,98-108,110 and 112-115* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7-28-2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 78 and 98-115 are pending.

Election/Restrictions

Applicant's election of a) a high-density lipoprotein cholesterol as the therapeutic agent species and b) a bioreactor formation catheter as the injection means species in the reply filed on 6/13/2011 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

However after search and consideration of the claims, the therapeutic agent species election has been withdrawn. As such claims 109 and 11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claims 78, 98-108, 110 and 112-115 are currently under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 115 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Said claim includes the limitation "reconstituting the cellular component", however the claims do not include for example, a lyophilization step or that the cellular component is in freeze dried form where reconstitution would be necessary. There is insufficient antecedent basis for this limitation in the claim.

Correction is respectfully requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 78, 98, 101 and 103 are rejected under 35 U.S.C. 102(b) as being anticipated by Pierce et al. (US Patent Pub. No. 2001/0044413 A1, Nov. 22, 2001, hereinafter referred to as "Pierce").

It should be noted that the instant claims are drawn to a method of using and includes product-by-process limitations. As such, determination of patentability is based on the method of using the product itself, not by the method in which the product is made. If the method of using the product in the product-by-process limitations are the same as or obvious from a method of using a product of the prior art, the claim is unpatentable even though the prior method of using the product was made by a different process (MPEP § 2113).

Regarding instant claim 78, Pierce teaches in situ bioreactors adapted for systemic delivery of bioactive agents, comprising a biocompatible substance, a first nucleic acid molecule encoding a cell growth stimulating agent, and a second nucleic acid molecule encoding a bioactive agent (abstract; paragraph [0009]). Pierce teaches the particular biocompatible substance, alginate (paragraphs [0015], [0016], [0061]-[0063], [0065] and [0069]; claims 56, 67 and 101). Pierce also teaches said bioreactors are used to treat a variety of diseases and medical conditions (paragraphs [0119]-[0128]).

Regarding instant claim 98, Pierce teaches injecting a composition comprising alginate directly into the patient that hardens when it comes into contact with a cross-linking agent such as calcium (paragraph [0062]).

Regarding instant claim 101, as discussed above, Pierce teaches bioreactors adapted for systemic delivery. A particular substance taught to be used in the bioreactor is alginate as a matrix material. Alginate is biodegradable and as such as it degrades, the bioactive will be released. Thus, the alginate bioreactor of Pierce inherently controls the elution of the bioactive.

Regarding instant claim 103, Pierce teaches various bioactives including VEGF, an angiogenic agent, a hormone, a protein, insulin and BMP (paragraphs [0009], [0012], [0018], [0021] and [0033]).

Thus, the teachings of Pierce render the instant claims anticipated.

Claims 78 are 101 are rejected under 35 U.S.C. 102(b) as being anticipated by Kwon et al. (US Patent Pub. No. 2002/0051821 A1, May. 2, 2002, hereinafter referred to as "Kwon").

It should be noted that the instant claims are drawn to a method of using and includes product-by-process limitations. As such, determination of patentability is based on the method of using the product itself, not by the method in which the product is made. If the method of using the product in the product-by-process limitations are the same as or obvious from a method of using a product of the prior art, the claim is unpatentable even though the prior method of using the product was made by a different process (MPEP § 2113).

Kwon teaches gelled alginate particles suitable for needless injection that are loaded with an active agent (abstract). Kwon teaches said alginate particles can be used to treat a variety of medical conditions (paragraphs [0055], [0056] and [0058]). Kwon teaches that the drug-loaded alginate particles are made by a) providing an aqueous solution or dispersion of an active agent and dissolving a water-soluble alginate therein, b) mixing the aqueous solution or dispersion with a solvent to form an emulsion, c) adding a divalent or trivalent metal cation which gels the alginate, d) collecting the particles and administering said particles via injection (paragraphs [0014]-[0017]). Kwon also teaches release of the active agents depends on several factors including the alginate matrix (paragraph [0026]); instant claim 101).

Thus, the teachings of Kwon render the instant claims anticipated.

Claims 78, 98, 101, 103-106 are rejected under 35 U.S.C. 102(b) as being anticipated by Viegas et al. (US Patent No. 5,124,151, Jun. 23, 1996, hereinafter referred to as " Viegas").

It should be noted that the instant claims are drawn to a method of using and includes product-by-process limitations. As such, determination of patentability is based on the method of using the product itself, not by the method in which the product is made. If the method of using the product in the product-by-process limitations are the same as or obvious from a method of using a product of the prior art, the

claim is unpatentable even though the prior method of using the product was made by a different process (MPEP § 2113).

Viegas teaches thermo-irreversible gels as vehicles for drug injection into the body of a mammal for treating a condition (abstract; claim 1). Viegas teaches an aqueous mixture comprising a polyoxyalkylene polymer, an ionic polysaccharide (e.g., alginate), a counter-ion (e.g., divalent calcium, strontium, barium) and a drug, wherein the aqueous mixture can be injected into the mammal as a low viscosity liquid and upon contact with the mammalian body, a semi-solid gel forms (col. 2, lines 56-65; col. 3, lines 15-20; col. 7, lines 41-58; Example 2). Viegas also teaches various bioactives including antineoplastic agents, anti-inflammatory agents, insulin and so on (col. 9, line 50 – col. 11, line 31; instant claim 103). Viegas further teaches an alternative method of making the gels by adding the counter-ion after injecting the polymer/polysaccharide/drug solution (col. 8; instant clam 106).

Thus, the teachings of Viegas render the instant claims anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly

owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 78 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pierce et al. (US Patent Pub. No. 2001/0044413 A1, Nov. 22, 2001, hereinafter referred to as "Pierce") in view of Bouhadir et al. (WO 9812228 A1, Mar. 26, 1998, hereinafter referred to as "Bouhadir").

It should be noted that the instant claims are drawn to a method of using and includes product-by-process limitations. As such, determination of patentability is based on the method of using the product itself, not by the method in which the product is made. If the method of using the product in the product-by-process limitations are the same as or obvious from a method of using a product of the prior art, the claim is unpatentable even though the prior method of using the product was made by a different process (MPEP § 2113).

Pierce teaches in situ bioreactors adapted for systemic delivery of bioactive agents, comprising a biocompatible substance, a first nucleic acid molecule encoding a cell growth stimulating agent, and a second nucleic acid molecule encoding a bioactive agent (abstract; paragraph [0009]). Pierce teaches the particular biocompatible substance, alginate (paragraphs [0015], [0016], [0061]-[0063], [0065] and [0069]; claims 56, 67 and 101). Pierce also teaches said bioreactors are used to treat a variety of diseases and medical conditions (paragraphs [0119]-[0128]).

Pierce is silent to a ratio of mannuronate alginate subunits to guluronate alginate subunits.

Bouhadir teaches injectable compositions comprising alginates for cell transplantation, tissue engineering and drug delivery applications (abstract; pages 1-3). Bouhadir further teaches tailoring the alginate composition by modifying, for example, the ratio of mannuronate and guluronate units (page 10, line 25 – page 11, line 26). Bouhadir explains that such a modification provides controllability of the composition, for instance, in injectable formulations, the ratio modifications allow for increasing or

decreasing the rate of gelation such that the alginate solution will gel at the appropriate time after injection (page 11, lines 9-26).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to optimize the ratio of mannuronate alginate subunits to guluronate alginate subunits in the injectable alginate composition taught by Pierce with a reasonable expectation of success because Bouhadir teaches modification of the ratio of mannuronate alginate subunits to guluronate alginate subunits effectively allows one to control and manipulate the rate of gelation such that the alginate solution will gel at the desired time after injection.

Thus, the combined teachings of Pierce and Bouhadir render the instant claims *prima facie* obvious.

Claims 78 and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viegas et al. (US Patent No. 5,124,151, Jun. 23, 1996, hereinafter referred to as " Viegas").

It should be noted that the instant claims are drawn to a method of using and includes product-by-process limitations. As such, determination of patentability is based on the method of using the product itself, not by the method in which the product is made. If the method of using the product in the product-by-process limitations are the same as or obvious from a method of using a product of the prior art, the claim is unpatentable even though the prior method of using the product was made by a different process (MPEP § 2113).

Viegas teaches thermo-irreversible gels as vehicles for drug injection into the body of a mammal for treating a condition (abstract; claim 1). Viegas teaches an aqueous mixture comprising a polyoxyalkylene polymer, an ionic polysaccharide (e.g., alginate), a counter-ion (e.g., divalent calcium, strontium, barium) and a drug, wherein the aqueous mixture can be injected into the mammal as a low viscosity liquid and upon contact with the mammalian body, a semi-solid gel forms (col. 2, lines 56-65; col. 3, lines 15-20; col. 7, lines 41-58; Example 2). Viegas also teaches various bioactives including antineoplastic agents, anti-inflammatory agents, insulin and so on (col. 9, line 50 – col. 11, line 31; instant

claim 103). Viegas further teaches an alternative method of making the gels by adding the counter-ion after injecting the polymer/polysaccharide/drug solution (col. 8; instant clam 106).

Viegas is silent to "wherein the alginate liking agent is deposited in the portion of the mammalian body prior to injecting the alginate solution".

Viegas teaches administering the linking agent separately (e.g., the linking agent being encapsulated in a controlled release composition) from the aqueous mixture in various ways but is not explicit whether one is administered before the other (col. 8). Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to administer the linking agent and aqueous mixture in any order with a reasonable expectation of success because a reaction cannot occur until they meet and react and controlled-release of the counter ion would allow time for the aqueous mixture to be administered.

Thus, the teachings of Viegas render the instant claims obvious.

Claims 78, 99, 100 and 112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viegas et al. (US Patent No. 5,124,151, Jun. 23, 1996, hereinafter referred to as " Viegas") in view of Bouhadir et al. (WO 9812228 A1, Mar. 26, 1998, hereinafter referred to as "Bouhadir").

Viegas teaches thermo-irreversible gels as vehicles for drug injection into the body of a mammal for treating a condition (abstract; claim 1). Viegas teaches an aqueous mixture comprising a polyoxyalkylene polymer, an ionic polysaccharide (e.g., alginate), a counter-ion (e.g., divalent calcium, strontium, barium) and a drug, wherein the aqueous mixture can be injected into the mammal as a low viscosity liquid and upon contact with the mammalian body, a semi-solid gel forms (col. 2, lines 56-65; col. 3, lines 15-20; col. 7, lines 41-58; Example 2). Viegas also teaches various bioactives including antineoplastic agents, anti-inflammatory agents, insulin and so on (col. 9, line 50 – col. 11, line 31; instant claim 103). Viegas further teaches an alternative method of making the gels by adding the counter-ion after injecting the polymer/polysaccharide/drug solution (col. 8; instant clam 106).

Viegas is silent to a ratio of mannuronate alginate subunits to guluronate alginate subunits.

Bouhadir teaches injectable compositions comprising alginates for cell transplantation, tissue engineering and drug delivery applications (abstract; pages 1-3). Bouhadir further teaches tailoring the alginate composition by modifying, for example, the ratio of mannuronate and guluronate units (page 10, line 25 – page 11, line 26). Bouhadir explains that such a modification provides controllability of the composition, for instance, in injectable formulations, the ratio modifications allow for increasing or decreasing the rate of gelation such that the alginate solution will gel at the appropriate time after injection (page 11, lines 9-26).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to optimize the ratio of mannuronate alginate subunits to guluronate alginate subunits in the injectable alginate composition taught by Viegas with a reasonable expectation of success because Bouhadir teaches modification of the ratio of mannuronate alginate subunits to guluronate alginate subunits effectively allows one to control and manipulate the rate of gelation such that the alginate solution will gel at the desired time after injection.

Thus, the combined teachings of Viegas and Bouhadir render the instant claims *prima facie* obvious.

Claims 78, 102-104 and 110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viegas et al. (US Patent No. 5,124,151, Jun. 23, 1996, hereinafter referred to as " Viegas") in view of Herrmann et al. (US Patent Pub. No. 2002/0094985 A1, Jul. 18, 2002, hereinafter referred to as "Herrmann").

It should be noted that the instant claims are drawn to a method of using and includes product-by-process limitations. As such, determination of patentability is based on the method of using the product itself, not by the method in which the product is made. If the method of using the product in the product-by-process limitations are the same as or obvious from a method of using a product of the prior art, the claim is unpatentable even though the prior method of using the product was made by a different process (MPEP § 2113).

Viegas teaches thermo-irreversible gels as vehicles for drug injection into the body of a mammal for treating a condition (abstract; claim 1). Viegas teaches an aqueous mixture comprising a polyoxyalkylene polymer, an ionic polysaccharide (e.g., alginate), a counter-ion (e.g., divalent calcium, strontium, barium) and a drug, wherein the aqueous mixture can be injected into the mammal as a low viscosity liquid and upon contact with the mammalian body, a semi-solid gel forms (col. 2, lines 56-65; col. 3, lines 15-20; col. 7, lines 41-58; Example 2). Viegas also teaches various bioactives including antineoplastic agents, anti-inflammatory agents, insulin and so on (col. 9, line 50 – col. 11, line 31; instant claim 103). Viegas further teaches an alternative method of making the gels by adding the counter-ion after injecting the polymer/polysaccharide/drug solution (col. 8; instant clam 106).

Viegas is silent to nitric oxide (instant claims 102 and 103).

Herrmann teaches local delivery of nitric oxide within the human body by way of a biodegradable matrix (abstract; paragraphs [0040], [0052] and [0053]). One preferred matrix material is alginate (paragraph [0062]).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include nitric oxide or a therapeutic agent comprising nitric oxide in the invention of Viegas with a reasonable expectation of success because Herrmann teaches effective local delivery of nitric oxide by way of an implantable alginate based matrix.

Viegas is also silent to injection via catheter (instant claim 110).

Herrmann teaches methods of administration via injection and infusion catheters (paragraph [0131]).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to administer the gel mixture of Viegas via a catheter with a reasonable expectation of success because Herrmann teaches local administration of a similar matrix material for the same purpose, that is, local drug delivery.

Thus, the combined teachings of Viegas and Herrmann render the instant claims obvious.

Claims 78, 104, 113 and 114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viegas et al. (US Patent No. 5,124,151, Jun. 23, 1996, hereinafter referred to as " Viegas") in view of Burg (US Patent Pub. No. 2002/0022883 A1, Feb. 21, 2002).

It should be noted that the instant claims are drawn to a method of using and includes product-by-process limitations. As such, determination of patentability is based on the method of using the product itself, not by the method in which the product is made. If the method of using the product in the product-by-process limitations are the same as or obvious from a method of using a product of the prior art, the claim is unpatentable even though the prior method of using the product was made by a different process (MPEP § 2113).

Viegas teaches thermo-irreversible gels as vehicles for drug injection into the body of a mammal for treating a condition (abstract; claim 1). Viegas teaches an aqueous mixture comprising a polyoxyalkylene polymer, an ionic polysaccharide (e.g., alginate), a counter-ion (e.g., divalent calcium, strontium, barium) and a drug, wherein the aqueous mixture can be injected into the mammal as a low viscosity liquid and upon contact with the mammalian body, a semi-solid gel forms (col. 2, lines 56-65; col. 3, lines 15-20; col. 7, lines 41-58; Example 2). Viegas also teaches various bioactives including antineoplastic agents, anti-inflammatory agents, insulin and so on (col. 9, line 50 – col. 11, line 31; instant claim 103). Viegas further teaches an alternative method of making the gels by adding the counter-ion after injecting the polymer/polysaccharide/drug solution (col. 8; instant clam 106).

Viegas is silent to harvesting a cellular component such as endothelial cells from a host or donor (instant claims 113 and 114).

Burg teaches an injectable composite comprising cells such as endothelial cells obtained from a patient in an alginate carrier for local delivery of said cells to aid in new tissue growth (claim 73; paragraphs [0003] and [0004]).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to harvest cells such as endothelial cells from a patient and include them in the injectable gel of Viegas with a reasonable expectation of success because Burg teaches incorporating said cells in an injectable composite comprising an alginate gel for the same purpose, that is, local delivery of a bioactive.

Thus, the combined teachings of Viegas and Burg render the instant claims obvious.

Conclusion

All claims have been rejected; no claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun G. Sajjadi, can be reached at 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey S Hagopian/
Examiner, Art Unit 1617

/Carlos A. Azpuru/

Primary Examiner, Art Unit 1617